

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC. and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.
and ZYDUS LIFESCIENCES LTD.,

Defendants.

C.A. No. 23-866-RGA-LDH

PROTECTIVE ORDER

WHEREAS Plaintiffs Par Pharmaceutical, Inc. and Endo Par Innovation Company, LLC (collectively, “Par” or “Plaintiffs”) and Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, “Zydus” or “Defendants”) (Plaintiffs and Defendants collectively, the “Parties”) agree that the nature of the above-captioned litigation (the “Action”) will require them to seek and produce documents and information, and elicit deposition testimony, the disclosure of which poses a substantial risk of harm to the Producing Party’s legitimate proprietary interests;

WHEREAS the Parties agree that this Protective Order is necessary to minimize the harm flowing from the disclosure of sensitive information; and

WHEREAS the Parties agree to the terms of this Protective Order to protect their confidential documents, things and information;

IT IS HEREBY ORDERED THAT the Parties and any non-party subject to discovery in this Action are bound by the terms of this Protective Order governing the production of Protected Material in this Action.

1. **Scope of Protective Order:** This Protective Order applies to all Discovery Materials produced by a Producing Party in connection with this Action. A Receiving Party may use Protected Material disclosed or produced by another Party or by a Non-Party only for prosecuting, defending, or attempting to settle this Action. Such Protected Material may be disclosed only to the categories of persons and under the conditions described in this Protective Order. In addition, this Protective Order allows for the filing of documents with the Court under seal, subject to any applicable Local Court Rule or CM/ECF procedure, if such documents contain Protected Material. This Protective Order shall apply regardless of whether such information was produced prior to or after entry of this Protective Order.

2. Definitions:

(a) **“Protected Material”** means any confidential, proprietary, or commercially sensitive information, including confidential, proprietary or sensitive design, development, technical, or manufacturing information, as well as any information which is not generally known and which the Producing Party would not normally reveal to third parties or would cause third parties to maintain in confidence and/or which the Producing Party reasonably and in good faith believes is of the type protectable under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure or is required to be kept confidential by law or by agreement with a third party or otherwise. “Protected Material” shall not include: (i) materials that show on their face that they have been disseminated to the public; or (ii) information that the Producing or Designating Party agrees, or the Court rules (a) is already public knowledge, (b) has become public knowledge other than as a result of disclosure by the Receiving Party, its employees or agents in violation of this Protective Order, or (c) has come into the Receiving Party’s legitimate knowledge or possession independently of the Producing Party under conditions such that its use and/or public disclosure by the Receiving Party would not violate any obligation to the Producing Party. Any summary, compilation, notes, memoranda, analysis or copy containing Protected Material and any electronic image or database containing Protected Material shall be considered Protected Material to the same extent as the material or information from which such summary, compilation, notes, copy, memoranda, analysis, electronic image, or database is derived. “Protected Material” shall mean and include any information, document, or tangible item that has been marked as either “Confidential” or “Highly Confidential” information, as provided herein. Any items of “Protected Material” shall bear only one of the two confidentiality designations.

(b) **“Confidential Information”** means any information (regardless of how it is generated, stored, or maintained) or tangible things, including but not limited to, any trade secrets or other research, development, commercial, or personnel information that is non-public and confidential or proprietary, the value of which arises from its secrecy. Identification of types of documents in this Paragraph shall not be an admission by any Party that such documents are relevant or admissible in this Action. Confidential Information may be contained in discovery information or materials produced or obtained in this Action by or through any means and by or through any persons or entity. Each Party shall act in good faith in designating information as “Confidential Information.” The term “Confidential Information” shall mean information (regardless of how it is generated, stored, or maintained) or tangible things that satisfies Paragraph 2(a). As stated in Paragraph 6, access to “Confidential Information” is limited to the persons defined in Paragraphs 2(l)(i)-(vi).

(c) **“Highly Confidential Information”** means any information (regardless of how it is generated, stored, or maintained) or tangible things that are so sensitive and confidential that disclosure, whether separately or in conjunction with other information being disclosed, is believed in good faith by the Producing Party to have the potential for causing competitive harm or giving a competitive advantage to others and access to such information should be more limited. The term “Highly Confidential Information” shall mean any information (regardless of how it is generated, stored, or maintained) or tangible things that satisfy Paragraph 2(b) and which comprises or contains the following particularly sensitive information of the Parties: future financial documents (for example, P&L statements), business

strategy, projected future sales, pricing, customer/vendor agreement, revenue, cost, or profit information for its products, documents concerning the research and development of any products other than the Parties' generic products at issue in this Action, and any other information a Producing Party believes in good faith could cause irreparable harm to its business if disclosed to personnel for the Receiving Party. Identification of types of documents in this paragraph shall not be an admission by any Party that such documents are relevant or admissible in this Action. Each Party shall act in good faith in designating information as "Highly Confidential Information." As stated in Paragraph 6, access to "Highly Confidential Information" is limited to the persons defined in Paragraphs 2(l)(ii)-(vi).

(d) **"Designating Party"** means any Party or Person who designates Discovery Material as "Confidential" or "Highly Confidential."

(e) **"Designated Materials"** means Discovery Material designated in accordance with Paragraph 4 of this Protective Order.

(f) **"Discovery Material"** means any documents, tangible or intangible information, or things (including, without limitation, any writings, video or audio tapes, text or application messages, computer-generated or recorded information in any form, metadata, materials, oral or written testimony, document requests, responses to document requests, and other responses to requests for information or any tangible thing) produced or disclosed by a Party or Non-Party in this Action.

(g) **"Non-Party"** means any natural person, partnership, corporation, association, or other legal entity not named as a Party in the above-captioned action.

(h) **"Outside Counsel"** means litigation counsel of record for the Parties, including associated personnel necessary to assist outside counsel in this Action, such as legal assistants, paralegals, secretarial, stenographic, information technology and clerical employees actually assisting such counsel; outside vendors that scan, code and/or produce documents at such counsel's request; translation services; computer services; and trial consultants, their employees, and independent contractors hired to assist them, other than those persons described in paragraph 2(l)(iii) below.

(i) **"Parties" or "Party"** mean the following plaintiffs and/or defendants in this civil action: Par Pharmaceutical, Inc., Endo Par Innovation Company, LLC, Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Ltd., and any other parties that may hereafter be named as additional plaintiffs or defendants in this Action.

(j) **"Person"** means any natural person or any business, legal or governmental entity or association.

(k) **"Producing Party"** means any Party or Person who produces or discloses any Discovery Material.

(l) **"Qualified Person"** means:

- i. Up to two (2) designated in-house legal personnel of Par Pharmaceutical, Inc. (“Par”) and Endo Par Innovation Company, LLC (“Endo”) and up to two (2) designated in-house legal personnel of Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) and Zydus Lifesciences Limited (“Zydus Lifesciences”), as well as their support staff, who have a need to know Confidential Information to fulfill their duties and responsibility in connection with this Action, provided such personnel have complied with Paragraph 9 hereof, the designated in-house legal personnel for Par and Zydus USA being as follows or as otherwise identified during the course of this Action:

For Par/Endo:

For Zydus USA/Zydus Lifesciences:

who, after receipt of Confidential Information, and in addition to the other terms of this Protective Order, shall not use any other Party’s or any Non-Party’s Confidential Information for any purpose other than in connection with this case, and shall not disclose any other Party’s or any nonparty’s Confidential Information to any third party, including, but not limited to, the United States Food & Drug Administration and the United States Patent and Trademark Office;

- ii. Outside Counsel;
- iii. outside independent experts and consultants of the Parties who are assisting Outside Counsel in this Action and any necessary assistants and stenographic and clerical employees under their direct supervision and employed by them or their employer or organization, provided that any applicable requirements of Paragraph 8(a) below are satisfied;
- iv. any mediators agreed upon by the Parties, including regularly employed support personnel of the mediator (such as administrative assistants, secretaries, clerical, and administrative staff) as necessarily incident to the mediation process;
- v. the Court, its personnel, jurors and alternate jurors, and court reporters, stenographers and videographers transcribing or recording testimony at depositions, hearings or trial in this Action; and
- vi. any other person with prior written consent of the Producing Party.

(m) **“Receiving Party”** means any Person to whom Protected Material is disclosed in this Action.

(n) **“This Action”** means the above-captioned action.

(o) **“This Court”** means the United States District Court for the District of Delaware.

3. **Bar:** Qualified Persons authorized to receive Protected Material shall have no current involvement and shall not have involvement for the duration of this litigation in any of the following activities: (i) the prosecution of any patent or patent application concerning varenicline (it being understood that Qualified Persons may disclose art for use in prosecution and may participate in post-grant review proceedings, including *inter partes* reviews (IPRs), post-grant reviews (PGRs), reexaminations, or reissues, except that no Qualified Person shall be involved directly or indirectly in seeking amendment of the claims in any such post-grant review proceedings); and (ii) the preparation or submission of any FDA documents (including but not limited to Citizen Petitions) regarding approval requirements relating to varenicline, except Qualified Persons may have involvement in responding to any Citizen Petitions regarding approval requirements relating to varenicline. For the avoidance of doubt, nothing in this paragraph shall be construed to limit Qualified Persons from communicating with FDA or any other regulatory or governmental authority in good faith regarding health, safety, or efficacy matters related to varenicline, pursuant to court order, or as otherwise requested by the FDA or required by applicable law or regulation.

4. **Designation of Protected Material:**

- (a) Discovery Material, or any relevant portion of any letter, brief, motion, affidavit, discovery response, discovery request, or other pleading, may be designated by any Producing Party as “Highly Confidential-Outside Counsel’s Eyes Only” or “Confidential-Pursuant to Protective Order” provided the material meets the definitions thereof provided herein.
- (b) Such designation shall be made or supervised by an attorney and shall be based on a good faith belief that Discovery Material so designated is entitled to protection under the terms of this Protective Order. Any information supplied in documentary or other tangible form may be designated by the Producing Party, or other Person claiming that the information is Protected Material, by placing or affixing on each page of such Document, or on the face of such thing, the legend “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY PURSUANT TO PROTECTIVE ORDER” or “CONFIDENTIAL – PURSUANT TO PROTECTIVE ORDER.”
- (c) Confidential or Highly Confidential Testimony: Testimony obtained from a deposition may be designated “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY” or “CONFIDENTIAL – PURSUANT TO PROTECTIVE ORDER” when appropriate, either on the record at the deposition or by letter or by email to all counsel of record and the reporter within twenty (20) days after receipt of the final (i.e., not “draft” or

“rough”) transcript. Subject to any requirements of the Court, the reporter for any deposition shall affix a mark of “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY” or “CONFIDENTIAL – PURSUANT TO PROTECTIVE ORDER” to pages that contain testimony designated as such. All such transcripts shall be treated as Protected Material until designated otherwise or until the time to so designate has expired as set forth in this provision, whichever is later.

- (d) With respect to testimony elicited during hearings, trial, or other court proceedings, whenever counsel for any Party deems that any question or line of questioning calls for the disclosure of Protected Material, counsel may state on the record that such disclosure is subject to this Protective Order. Whenever Protected Material is to be discussed in a hearing or other proceeding, any Party claiming such protection may ask the Court to have excluded from the hearing or other proceeding any person who is not permitted access to the Protected Material pursuant to this Protective Order and/or seek to redact portions of the transcript reflecting Protected Material.

5. **Publicly Available Material:** Discovery Material that has been produced to or prepared by or for, any government agency that is available to the public, either by the Freedom of Information Act or any other federal or state law, and Discovery Material which is otherwise available to the public from any source, should not be designated as Protected Material. If a Party receives material designated “Highly Confidential-Outside Counsel’s Eyes Only” or “Confidential-Pursuant to Protective Order” that the Party believes falls under this Paragraph, the Party may challenge the designation and request relief from the Court, after conferring in good faith with counsel for the Producing Party. If the Party seeks relief from the Court, until the Court rules on the requested relief, the Discovery Material shall be treated as Protected Material. The Party or Person claiming that the material is Protected Material bears the burden of establishing the confidentiality of the so-designated materials.

6. **Nondisclosure of Protected Material:** Except with the prior written consent of the Designating Party or as provided in this Protective Order, no Confidential Information may be disclosed to any Party or Person, other than a Qualified Person under Paragraph (2)(1)(i)-(vi). Except with the prior written consent of the Designating Party or as provided in this Protective Order, no Highly Confidential Information may be disclosed to any Party or Person, other than a Qualified Person under Paragraph 2(a)(ii)-(vi). No Protected Material may be disclosed to any Person engaged in the activities set forth in Paragraph 3, except as set forth therein.

7. **Disclosure of Protected Material:** Any information designated as Protected Material shall be maintained in confidence by any Receiving Party and may be disclosed to Qualified Persons only as permitted under the terms of this Protective Order. Prior to any disclosure to Qualified Persons in category 2(1)(i) and (iii) above, the relevant requirements of Paragraph 8 below shall be satisfied, including that each such Qualified Person shall read this Protective Order and sign Exhibit A or Exhibit B attached hereto. The Party that has retained, or disclosed Protected Material to, the Qualified Persons shall retain a copy of the executed Undertaking(s) until the final resolution of this Action.

8. Disclosure of Protected Material to Designated In-House Legal Personnel and Experts and Consultants:

(a) Designated In-House Legal Personnel. The following applies for each designated in-house legal personnel, described in Paragraph 2(l)(i) above to whom Confidential Information is to be disclosed in any way:

- i. Such designated in-house legal personnel shall first read this Protective Order and sign Exhibit A attached hereto.
- ii. At least seven (7) business days prior to the Receiving Party disclosing Confidential Information to any designated in-house legal personnel, the Receiving Party shall deliver (by electronic mail) to all other Parties a copy of the signed Exhibit A; and shall state the person's name and position.
- iii. If a Party has a good faith basis for believing it would be harmed by the proposed disclosure, the Party shall object to such disclosure within five (5) business days after service of the information called for in Paragraph 8(a)(ii). Objections must be in writing and state with particularity the basis for the objection.
- iv. In the event of such an objection, the Parties shall meet and confer within three (3) business days to attempt to resolve the concerns giving rise to the objection. If the parties are unable to reach an agreement regarding such disclosure, the Party objecting to disclosure may, within five (5) business days of the meet and confer, request that the Court issue an order barring such disclosure. The objecting Party shall have the burden of showing why that person should not have access to Confidential Information. Pending resolution of any such motion or application, no disclosure of Confidential Information shall be made to that person. The filing and pendency of such motion shall not limit, delay or defer any disclosures of Confidential Information to persons as to whom no such objection has been made.

(b) Independent Experts and Consultants. The following applies for each independent expert and consultant, including nontestifying experts and consultants, described in Paragraph 2(l)(iii) above to whom Protected Material is to be disclosed in any way:

- i. Such expert or consultant shall first read this Protective Order and sign the Exhibit B attached hereto.
- ii. At least seven (7) business days prior to the Receiving Party disclosing Protected Material to any expert or consultant, the Receiving Party shall deliver (by electronic mail) to all other Parties (1) a copy of the signed Exhibit B; (2) a resume or

curriculum vitae; and (3) to the extent not provided for in the resume or curriculum vitae, the person's (a) name, (b) residence and office addresses, (c) present employer, job title, and job description, (d) a list of cases in which the person has testified (including by declaration, report, or at trial or deposition) in the last four years, and (e) a brief job history for the past five years.

- iii. If a Party has a good faith basis for believing it would be harmed by the proposed disclosure, the Party shall object to such disclosure within five (5) business days after service of the information called for in Paragraph 8(b)(ii). Objections must be in writing and state with particularity the basis for the objection.
- iv. In the event of such an objection, the Parties shall meet and confer within three (3) business days to attempt to resolve the concerns giving rise to the objection. If the parties are unable to reach an agreement regarding such disclosure, the Party objecting to disclosure may, within five (5) business days of the meet and confer, request that the Court issue an order barring such disclosure. The objecting Party shall have the burden of showing why that person should not have access to Protected Material. Pending resolution of any such request, no disclosure of Protected Material shall be made to that person. The filing and pendency of such request shall not limit, delay or defer any disclosures of Protected Material to persons as to whom no such objection has been made.

9. Use of Designated Materials:

(a) Subject to Paragraph 16 below, Protected Material shall be used by the Receiving Party solely for the purposes of preparation for trial, pretrial proceedings, and trial of actions and proceedings in this Action, and not for any business, commercial, regulatory, competitive, personal, or other purpose or any other action, including without limitation that Protected Material disclosed in this litigation shall not be used in: (i) any other action, including lawsuits against FDA; (ii) the prosecution of any patent or patent application, including reexaminations, reissues, and seeking claim amendments in any post-grant review proceedings (IPRs and PGRs); (iii) the preparation or submission of any United States FDA documents (including but not limited to Citizen Petitions), or any similar documents in any foreign country; (iv) and marketing, financial, pricing, or other business competitive decision-making (not including settlement or other decision-making in the Action); and (v) preparing submissions to the *U.S. Pharmacopeia* or *European Pharmacopeia*.

(b) Protected Material may be disclosed by a Receiving Party during a deposition, to the extent that its use is reasonably necessary, at the depositions of the following:

- i. The present directors, officers, employees, agents, or Rule 30(b)(6) designees of the Producing Party;

- ii. An author, addressee, or other person indicated as a lawful recipient of a document containing the information;
- iii. A person not within subparagraphs 8(b) above who is clearly identified in prior discovery or by the deponent in his or her deposition as an author or recipient of the information (without prior disclosure of the Protected Material);
- iv. An independent advisor, consultant, expert or other Qualified Person entitled under this Protective Order to receive such information;
- v. Any person for whom prior authorization is obtained from the Producing Party or the Court; or
- vi. Individuals who have been identified through discovery (including document production, written discovery or deposition testimony) as having knowledge of the particular Protected Material, even if the individual is not identified as an actual author or recipient on the face of the document at issue.

(c) During depositions of any Party or Non-Party, a Party or Non-Party claiming that information that is to be disclosed or upon which questions may be based is Protected Material may exclude from the room for that portion of the deposition any person who is not permitted to access such Protected Material under the terms of this Protective Order.

10. No Waiver of Protection:

(a) In the event any document is produced that the Producing Party later claims is protected by the attorney-client privilege, work-product doctrine, or other privilege or immunity, the Receiving Party shall, as soon as possible but not later than within five (5) business days of receipt of a written request by the Producing Party, return the original to the Producing Party (or at the option of the Receiving Party destroy the original with written verification provided to Outside Counsel for the Producing Party), destroy or delete all copies thereof, as well as all notes, memoranda or other documents that summarize, discuss or quote the document, and delete any copy of the document, or any portion thereof, from any word processing or database tape or disk it maintains. Upon receiving notice of inadvertent production, the Receiving Party(ies) shall not make any use of such document or thing or disseminate the same in any way. The unintentional or inadvertent production of privileged, work-product-protected or otherwise immune documents in the course of discovery in this Action shall not constitute a waiver of any privilege, work-product-protection or immunity, either as to the produced document or as to any other documents or communications embracing the same or similar subject matter provided that the Producing Party notifies the Receiving Party in writing of such unintentional or inadvertent production by the earlier of: seven (7) days after the date the unintentional or inadvertent production is discovered; or seven (7) days after the date the information is used at a deposition, included or cited in a court filing, or included in contentions or expert discovery exchanged between the Parties. Return of a document for which

the Producing Party has asserted a claim of privilege, work-product-protection or immunity under this paragraph shall be without prejudice to the Receiving Party's right to seek an order from the Court directing production of the document on the ground that the claimed privilege, work-product-protection or immunity is invalid, inapplicable or waived, provided, however, that any motion or other application for such order shall not rely upon in any manner or assert as a ground the fact or circumstances of the unintentional or inadvertent production, nor shall it disclose the substance of the inadvertently produced material except to the extent that an *in camera* inspection of the materials is requested. The Producing Party shall be required to promptly notify the Receiving Party of discovery of any inadvertently produced privileged documents upon discovery of the inadvertent production.

(b) Nothing herein shall prevent the Receiving Party from preparing and keeping a record containing the date, author, email address(es), and such other metadata as is reasonably necessary to identify a document or communication a Producing Party later claims is protected by the attorney-client privilege, work-product doctrine, or other privilege or immunity in order to seek relief compelling the production of the information. Such a record may not be used for any purpose other than the preparation and filing of a request to compel. After the return or destruction such a document or communication, the Receiving Party may challenge the Producing Party's claim(s) of privilege or immunity by making an application to the Court.

(c) Unintentional or inadvertent failure to designate any information as Protected Material pursuant to this Protective Order shall not constitute a waiver of any otherwise valid claim for protection, provided that the Producing Party notifies the Receiving Party in writing of such unintentional or inadvertent failure to designate by the earlier of: seven (7) days after the date the unintentional or inadvertent production is discovered; or seven (7) days after the date the information is used at a deposition, included or cited in a court filing, or included in contentions or expert discovery exchanged between the parties. In the event of an unintentional or inadvertent failure to designate any information, arrangements shall be made for the return to the Producing Party, or the destruction or deletion of, all copies of the unintentionally or inadvertently undesignated information and for the substitution, where appropriate, of properly labeled copies.

(d) Review of Protected Material as permitted in this Protective Order in connection with this Action shall not waive the confidentiality of the information or objections to production. The inadvertent, unintentional, or *in camera* disclosure of Protected Material shall not, under any circumstances, be deemed a waiver, in whole or in part, of any Party's claims of confidentiality.

(e) Should any Protected Material be disclosed to any person not entitled to receive the same hereunder, the information shall not lose its protected status through such disclosure, and the parties shall exercise their best efforts and take all steps reasonably required to protect its confidentiality after such inadvertent disclosure. If Protected Material is disclosed to any person other than in the manner authorized by this Protective Order, the party responsible for the disclosure shall within five (5) calendar days of learning of such disclosure inform the Producing Party of the inadvertent disclosure. As soon as possible thereafter, the parties shall also use reasonable efforts to obtain the prompt return of any such Protected Material and obtain a signed Exhibit A or Exhibit B, as applicable, attached hereto from each unauthorized person or

party who received Protected Material. Nothing herein shall prevent the Producing Party from applying to the Court for further or additional relief.

11. **Redactions:** Documents and things produced or made available for inspection may be subject to redaction, in good faith by the Producing Party, of (i) information that relates to drug products that do not contain varenicline and is not otherwise relevant to this Action or reasonably likely to lead to the discovery of admissible evidence in this Action, (ii) confidential personally identifiable information (e.g., social security numbers, patient names, dates of birth), or (iii) information that is subject to the attorney-client privilege or to the work-product immunity. Each such redaction, regardless of size, shall be clearly labeled. All documents redacted for privilege shall be listed on a redaction log stating the basis for such redaction. This paragraph shall not be construed as a waiver of any Party's right to seek disclosure of redacted information.

12. **Filing:** All documents – including pleadings, motions and other papers – containing Protected Material shall be filed with the Court under seal in accordance with the Court's Local Rules and CM/ECF procedures.

13. **Challenges to Confidentiality Designations and Requests to Disclose Protected Material to Non-Parties:** If the Receiving Party desires to disclose Protected Material to someone other than a Qualified Person above, or if the Receiving Party disagrees with the confidentiality designation by the Producing Party, then the Receiving Party shall so notify, in writing, Outside Counsel for the Person or Party asserting the confidentiality of the information. Outside Counsel for the Person or Party asserting the confidentiality of the information and the Receiving Party shall first try to resolve such dispute within five (5) business days after receipt of the Receiving Party's notice. If the dispute cannot be resolved, the Receiving Party, upon no fewer than three (3) business days written notice to the Person or Party asserting the confidentiality, may seek a ruling from the Court that the information is improperly designated or that such disclosure should take place because the interest of the Person or Party asserting the confidentiality in limiting the dissemination of the information is outweighed by the need for such disclosure. Pending a determination by the Court, such information shall be treated as Protected Material as designated by the Person or Party asserting the confidentiality claim. All Protected Material is entitled to confidential treatment pursuant to the terms of this Protective Order until and unless the parties formally agree in writing to the contrary or a contrary determination is made by the Court.

14. **Preservation of the Right to Challenge Confidentiality Designation:** No Party shall be obligated to challenge the propriety of a confidentiality designation, and a failure to do so shall not preclude a subsequent challenge to the propriety of such designation. This Protective Order shall be without prejudice to the right of any Party or other subscriber to this Protective Order (a) to bring before the Court at any time the question of whether any particular document or information is Protected Material or whether its use otherwise should be restricted or (b) to present a motion to the Court under Fed. R. Civ. P. 26(c), for a separate protective order as to any such particular document or information, including restrictions differing from those specified herein.

15. **Other Proceedings:**

(a) By entering this Protective Order and limiting the disclosure of information in this Action, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any Person or Party subject to this Protective Order who becomes subject to a motion to disclose another Party's information designated as Protected Material pursuant to this Protective Order shall promptly notify that Party of the motion so that the Party may have an opportunity to appear and be heard on whether that information should be disclosed.

(b) In the event any Receiving Party having possession, custody, or control of any Protected Material received from a non-party to this Action a subpoena or other process or order or discovery request to produce such information in another, unrelated legal proceeding, such party (i) shall notify counsel for the Designating Party of the subpoena or other process or order or discovery request, and (ii) shall not produce or disclose the information until the Designating Party has had reasonable time (at least fourteen (14) calendar days, unless the deadline to respond to the subpoena or other process or order or discovery request is earlier) to object or take other appropriate steps to protect the information. The Designating Party shall have the burden of defending against such subpoena or other process, order, or discovery demand.

16. **Client Consultation:** Nothing in this Protective Order shall prevent or otherwise restrict Outside Counsel from rendering advice to their clients and, in the course thereof, relying generally on examination of Protected Material produced in discovery in this Action; provided, however, that in rendering such advice and otherwise communicating with such clients, Outside Counsel shall not make specific disclosure of any item so designated except as permitted herein.

17. **Modification Permitted:** Nothing in this Protective Order shall prevent any Party or other Person from seeking modification of this Protective Order, from objecting to discovery that it believes to be otherwise improper, from applying to the Court for relief therefrom, or from applying to the Court for further or additional protective orders, or from agreeing among themselves to modify or vacate this Protective Order, subject to the approval of the Court. The Court retains jurisdiction even after termination of this Action to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may from time to time deem appropriate.

18. **Responsibility of Attorneys:** Outside Counsel for each respective Party are responsible for employing reasonable measures, consistent with this Protective Order, to control duplication of, access to, and distribution of copies of Protected Material received by them.

19. **Purpose Is to Facilitate the Exchange of Information:** This Protective Order is entered solely for the purpose of facilitating the exchange of information between the Parties to this Action without involving the Court unnecessarily in this process. Nothing in this Protective Order, nor the production of any documents or disclosure of any information pursuant to this Protective Order, shall be deemed to have the effect of (a) an admission or waiver, including waiver under the Federal Rules of Evidence or applicable Local Rules, by any Party or other subscriber to this Protective Order; (b) altering the confidentiality of any such information; or (c) altering any existing obligation of any party or other subscriber, or the absence of such obligation.

20. **Termination of the Action:** Within 90 days after the final conclusion of this Action, including all appeals, all Discovery Materials designated Protected Material, and all copies of the same, shall be returned to the Producing Party or, at the option of the Receiving Party, destroyed. This includes all notes, memoranda or other documents that summarize, discuss or quote materials or information produced and designated Protected Material, except that, with respect to word processing and database tapes and disks, the Receiving Party shall destroy or erase such tapes or disks to the extent practicable. Outside Counsel for each Party shall be entitled to retain copies of all filings, their work product, any transcripts of depositions, hearings or trial testimony, expert reports, written discovery or discovery responses, as well as documents that have been marked as exhibits to a deposition and documents included on trial exhibit lists and that contain or refer to information designated as Protected Material in this Action provided that all such documents shall remain subject to this Protective Order. Outside Counsel of record shall make certification of compliance herewith and shall deliver the same to Outside Counsel for the party that produced the documents not more than 120 days after conclusion of this Action, including all appeals.

21. **Return or Destruction of HIPAA Information:** Notwithstanding the foregoing, a Receiving Party may not retain an archival copy of any documents for which the Producing Party has notified the Receiving Party that such documents contain information protected by the Health Insurance Portability and Accountability Act (“HIPAA”). Accordingly, within thirty (30) days after final termination of this Action, including any appeals, a Producing Party shall identify all exhibits containing information protected by HIPAA that are contained within deposition transcripts, deposition exhibits, Court transcripts, Court exhibits and other submissions to the Court. Within thirty (30) calendar days of receipt of such identification, the Receiving Party shall either return to outside counsel for the Producing Party or destroy such exhibits and certify in writing to outside counsel for the Producing Party.

22. **No Limitations on Party’s Use of its Own Information:** This Protective Order shall not limit a Producing Party’s use of its own Protected Material.

23. **Third Parties:** If a third party provides Discovery Materials to any Party, such third party may adopt the terms of this Protective Order with regard to the production of any Protected Material by executing a Notice of Election to Adopt Stipulated Order on Confidentiality Agreement and Protective Order (“Notice of Election”) in the form attached hereto. In the event of such election, the provisions of this Protective Order shall apply to such Discovery Materials as if such Discovery Materials were being provided by a Party to this Action. Under such circumstances, the third party shall have the same rights and obligations under this Protective Order as held by the Parties to this Action.

24. **Information Not Covered by this Protective Order:** The restrictions set forth in this Protective Order will not apply to Protected Material that is in the possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party, or which comes into the lawful possession of or becomes known to the Receiving Party or comes into the possession of or otherwise becomes known to the public after the date of its transmission to the Receiving Party, provided that, as shown in written records, such information does not become publicly known by any act or omissions of the Receiving

Party which would be in violation of this Protective Order or otherwise violate any confidentiality obligation owed to a Party.

25. **Protective Order Remains in Force:** This Protective Order shall remain in force and effect until modified, superseded, or terminated by consent of the Parties or by order of the Court made upon reasonable written notice. Unless otherwise ordered, or agreed upon by the Parties, this Protective Order shall survive and remain in full force and effect after termination of this Action. Neither the termination of this Action nor the termination of employment of any person with access to any Protected Material shall relieve such person from the obligation of maintaining the confidentiality of such information.

26. **Pending Entry by the Court:** Until such time as this Protective Order has been entered by the Court, the parties agree that upon execution by the parties, it will be treated as though it had been "So Ordered."

The undersigned Outside Counsel stipulate that the Court should enter the above Protective Order as an order of the Court, and further stipulate that the Protective Order shall constitute a binding contract among the Parties and their Outside Counsel.

AGREED AND STIPULATED TO:

DATED: November 22, 2023

Respectfully submitted,

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

FARNAN LLP

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*Attorneys for Plaintiffs Par Pharmaceutical, Inc.
and Endo Par Innovation Company, LLC*

SO ORDERED, this 27th day of November, 2023.

/s/ Richard G. Andrews

The Honorable Richard G. Andrews
United States District Court Judge

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.
and ZYDUS LIFESCIENCES LTD.,

Defendants.

C.A. No. 23-cv-866-RGA-LDH

**UNDERTAKING AND ACKNOWLEDGEMENT OF
PROTECTIVE ORDER AND CONFIDENTIALITY STIPULATION**

I, _____, hereby attest as follows:

1. I understand that CONFIDENTIAL material may be disclosed to me under the terms of the Protective Order attached to this Undertaking and Acknowledgement. I have a copy of and have read the Order, and I agree to comply with and be bound by its terms. I also agree to be subject to the jurisdiction of this Court for the purpose of enforcing this Order and this agreement.

2. I agree that I will not disclose to anyone else the CONFIDENTIAL material disclosed to me, nor discuss or describe the substance or content of such material, except as provided in the Order, and that I will use such material only for the purposes of this litigation.

3. I agree that I will not keep any CONFIDENTIAL material or copies of any such material (including notes or other memoranda or writings containing or relating to such material)

except to the extent permitted by the Order, and, upon request, will destroy or return such material to the attorneys who disclosed such material to me.

Dated: _____

Signature

EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.
and ZYDUS LIFESCIENCES LTD.,

Defendants.

C.A. No. 23-cv-866-RGA-LDH

**UNDERTAKING AND ACKNOWLEDGEMENT OF
PROTECTIVE ORDER AND CONFIDENTIALITY STIPULATION**

I, _____, hereby attest as follows:

1. I understand that HIGHLY CONFIDENTIAL and CONFIDENTIAL material may be disclosed to me under the terms of the Protective Order attached to this Undertaking and Acknowledgement. I have a copy of and have read the Order, and I agree to comply with and be bound by its terms. I also agree to be subject to the jurisdiction of this Court for the purpose of enforcing this Order and this agreement.

2. I agree that I will not disclose to anyone else the HIGHLY CONFIDENTIAL and CONFIDENTIAL material disclosed to me, nor discuss or describe the substance or content of such material, except as provided in the Order, and that I will use such material only for the purposes of this litigation.

3. I agree that I will not keep any HIGHLY CONFIDENTIAL and CONFIDENTIAL material or copies of any such material (including notes or other memoranda or writings containing or relating to such material) except to the extent permitted by the Order, and, upon request, will destroy or return such material to the attorneys who disclosed such material to me.

Dated: _____

Signature

**NOTICE OF ELECTION TO ADOPT STIPULATED ORDER
ON CONFIDENTIALITY AGREEMENT AND PROTECTIVE ORDER**

1. _____, a non-party to the above-captioned litigation, has been requested and/or subpoenaed by a party to produce discovery containing Protected Material in connection with the above-captioned litigation.

2. _____ hereby elects to adopt the terms of the Stipulated Confidentiality Agreement and Protective Order (herein, the “Protective Order”) with regard to its terms regarding production of Protected Material.

3. The provisions of the Protective Order shall apply to all documents, things and other information produced by _____ as if such discovery were being provided by a party. _____ shall have the same rights and obligations under the Protective Order as held by the parties.

Dated: _____

Name

Company